Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>14 November 2005</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-28</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-28</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>10 August 2005</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 are presented for reconsideration in response to Office Action.

Response to Arguments

Applicant's arguments with respect to claim 28 have been considered but are moot in view of the new ground(s) of rejection.

35 USC 101 Rejection

Examiner thanks the Applicant for correcting the issues related to the 35 USC 101 rejection of claims 10-23. The rejection is therefore withdrawn.

Claims 1-9, 20, 25-28 under 35 USC 102(e)

Regarding claim 1:

Applicants argue that Tresp does not perform a simulation.

Note the definition of "simulation":

> Simulation. **Imitating or estimating how events might occur in a real situation.** It can involve complex mathematical modeling, role playing without the aid of technology, or combinations. The value lies in the placing you under realistic conditions, that change as a result of behavior of others involved so you cannot anticipate the sequence of events or the final outcome. (http://ag.arizona.edu/futures/home/glossary.html)

Furthermore, the Examiner traverses Applicant's argument that the simulation performed by Tresp does not perform numerical integration by citing **(col: 1 line: 51-65 "additive combination")**.

Claim 1 stands rejected.

Regarding claim 7, 25-28:

Applicants present same arguments as claim 1 above and are therefore rejected under same reasoning as above.

Regarding claims 1-9 and 25-28:

Applicants argue that claim 1 is allowable. Applicants' attention is drawn to the response to Applicants' arguments section "Regarding claim 1" above. Claim 1 stands rejected. Therefore, claims 1-9 and 25-28 remain rejected.

Regarding claim 20:

Applicants argue that Tresp does not disclose "a first biological process from the plurality of

biological processes being associated with metabolism of <u>at least two from the group of</u>

<u>carbohydrates, fats, and proteins.</u>"

Examiner traverses this argument. Specifically, noting paragraph cited by Applicants on page 16

(Tresp, Col. 2, lines 22-25):

> Determinant influencing variables for this blood sugar-insulin metabolism are, in detail, the times and dosage
> amounts of insulin injections, the times and amounts of food ingestion (basal insulin u.sub.t.sup.1 and normal
> insulin u.sub.t.sup.2), the times and amounts of food ingestion (fast ut3, <u>medium ut4</u> and **slow ut5**
> **carbohydrates**), the points in time and duration of physical exercise (regular u.sub.t.sup.6 or intensive
> u.sub.t.sup.7) and the blood sugar level y.sub.t (measured multiply per day).

The above-cited paragraph clearly shows two items from the group of carbohydrates, fats, and

proteins; the two items are <u>medium,</u> and **slow** carbohydrates.

Claim 20 stands rejected.

<div align="center">

Claims 10-15 Under 35 USC 102(b)

</div>

Regarding claim 10:

Applicants argue primarily that the definition of the term "defect" inconsistent with Brown.

Specifically, Applicants argue that the "term "defect" as used herein means an imperfection,

failure, or absence of a biological variable or a biological process associated with a disease state"

is inconsistent with Brown's "self-case parameters".

The definition of defect is:

> The term "defect" as used herein means an imperfection, failure, or absence of a
>
> ("biological variables") extra-cellular and/or intra-cellular constituents that make up a
>
> biological process or ("biological process") an interaction or series of interactions
>
> between biological variables associated with ("disease state") the result of the occurrence
>
> of a series of interactions between biological variables where one or more (biological
>
> process) interaction or series of interactions between biological variables are related to
>
> the cause or the clinical signs of the disease.

Indeed, insulin, listed as one of the self-care parameters. Patients measure the self-care

parameters' value and input that parameter into the system. As such, in a diabetic person, as

disclosed by Brown, the measure value is inherently imperfect. Furthermore, low/high insulin is a

result of extra-cellular and/or intra-cellular constituent that makes up a biological process (known

as metabolism). Furthermore, insulin indeed interacts with other biological processes and

variables (liver, kidneys, other organs). Furthermore, the result of a series of interactions

between biological variables results in clinical signs **(asthma, blood pressure in**

hypertension, cholesterol, etc) of the disease (diabetes). Therefore, insulin is indeed a

defect indicator.

Claim 10 stands rejected.

Regarding claims 11-15:

Applicants argue that claim 10 is allowable. Claim 10 stands rejected therefore claims 11-15

remain rejected.

Rejection of Claims 16-19 and 24 Under 35 USC 102(e)

Regarding claim 16:

Applicants argue primarily that the "Health States" and "Agents" described by Rivonelli are not a

defect indicator or a defect.

Applicants' attention is drawn to page 20 of the Office Action dated 8/10/05. Specifically noted is

Examiner's statement "when the generation method is performed, it provides a description of all

the findings defect". The Applicants improperly interpreted this statement. Specifically, Health

States and Agents are indeed not the defect indicators or defects; rather, the findings are the

defect indicators and defects. Examiner cites **(col: 6 line: 58-62)** as support for this argument.

Specifically, the finding "hyperglycemia" is the defect and defect indicator for the reasons

enumerated in section "Regarding claim 10".

Regarding claims 17-19:

Applicants argue that claim 16 is allowable. Claim 16 stands rejected therefore claims 17-19

remain rejected.

Rejection of claims 21-22 Under 35 USC 103(a)

Regarding claims 21-22:

Applicants argue that claim 20 above is allowable. Claim 20 above is rejected therefore claims

21-22 remain rejected.

Rejection of claim 23 Under 35 USC 103(a)

Regarding claim 23:

Applicants argue that claim 23 above is allowable. Claim 20 above is rejected therefore claims

21-22 remain rejected.

Claim Objections

Claims 10, 16, and 20 are objected to because of the following informalities:

there is a quote (") in the middle of the preamble; and

the preamble contain two transition phrases "further wherein" and "comprising".

Appropriate correction is required.

Claim Interpretation

With respect to claims reciting computer readable medium, it is noted that instructions, per se,

do not perform an action. Rather, the action is performed by the processor executing the

instructions and they will be interpreted as such. The Examiner respectfully suggests amending

the related claim preambles to clarify this matter.

Claim Rejections - 35 USC § 112

Where applicant acts as his or her own lexicographer to specifically define a term of a

claim contrary to its ordinary meaning, the written description must clearly redefine the claim

term and set forth the uncommon definition so as to put one reasonably skilled in the art on

notice that the applicant intended to so redefine that claim term. *Process Control Corp. v.*

HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term

"simulation" is used by the claims to mean "integration", while the accepted meaning is

"Imitating or estimating how events might occur in a real situation". The term is

indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis

for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 20, 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Volker Tresp

("Tresp" hereinafter) (US Patent 6,272,480).

As per claim 1, Tresp discloses a method for creating a computer model of diabetes, comprising:

identifying data relating to diabetes, the data relating changes in biological states to

biological attributes of diabetes **(col.: 1 lines: 18-29, column: lines: 2 lines 23-28**

"influence variables");

identifying a plurality of biological processes related to the data, the plurality of biological

processes defining at least one portion of the disease state of diabetes **(col.: 2 lines:**

24-26, col.: 4 lines: 33-41 "quantity of food" in the reference is directly related

to the quantity of protein, referring to disease state, col. 4 lines 24-26: to

> **warn a person a portion of the, or the whole, simulation result is used in**
>
> **conjunction with reference material to identify whether the said result is**
>
> **"showing" the disease state); and**
>
> combining the plurality of biological processes to form a simulation of glucose
>
> metabolism in the context of multiple macronutrient metabolism **(col.: 2 lines: 10-22,**
>
> **col.: 4 lines: 33-41 multiple macronutrient metabolism correlates to**
>
> **"carbohydrates" within the reference).**

As per claim 2, Tresp discloses a method of claim 1, further comprising:

> producing a simulated biological attribute associated with at least one biological attribute
>
> of diabetes from the combined plurality of biology processes based on the combined
>
> plurality of biology processes **(col.: 2 lines: 10-22);**
>
> comparing the simulated biological attribute with a corresponding biological attribute
>
> associated with a reference pattern of diabetes **(col.: 6 lines: 49-52, "risk analysis"**
>
> **inherently involves reference data taken from taken in a control environment**
>
> **from a diseased biological system, such data is then analyzed and compared**
>
> **to new/simulated result to assess the risks); and**
>
> identifying the computer model as a valid computer model of diabetes if the simulated
>
> biological attribute is substantially consistent with the biological attribute associated with
>
> a reference pattern of diabetes **(col.: 1 lines: 45-50 The computer model would**
>
> **inherently be substantially consistent when using a neural network and**
>
> **sufficient training data. As such it would be a valid model given its consistency**
>
> **to the reference pattern.)**

As per claim 3, Tresp discloses a method of claim 1, wherein the combining the plurality of

biological processes includes:

> forming a first mathematical relation among biological variables associated with a first
>
> biological process from the plurality of biological processes **(col.: 3 equation 1); and**

forming a second mathematical relation among biological variables associated with the first biological process and a second biological process from the plurality of biological variables associated with the plurality of biological processes (col.: 3 equation 2 Additionally, their associatively is shown in equation 3).

As per claim 4, Tresp discloses a method of claim 3, further comprising:

creating a set of parametric changes in the first mathematical relation and the second mathematical relation (col.: 5 lines: 44-49 training data, when introduced into the neural network will serve as a parametric change in the mathematical relations); and

producing a simulated biological attribute based on at least one parametric change from the set of parametric changes, the simulated biological attribute being substantially consistent with at least one biological attribute associated with a reference pattern of diabetes (col.: 5 lines: 59-61, col.: 6 lines: 32-36, col.: 1 lines: 45-50 The computer model would inherently be substantially consistent when using a neural network and sufficient training data. As such it would be a valid model given its consistency to the reference pattern.).

As per claim 5, Tresp discloses a method of claim 3, further comprising:

creating a set of parametric changes in the first mathematical relation (col.: 5 lines: 44-49 training data, when introduced into the neural network will serve as a parametric change in the mathematical relations)

and a set of parametric changes in the second mathematical relation, the set of parametric changes in the first mathematical relation being associated with a first diabetes defect having its own degree of severity (col.: 5 lines: 59-61, col.: 6 lines: 32-36, col.: 1 lines: 45-50 The computer model would inherently be substantially consistent when using a neural network and sufficient training

data. As such it would be a valid model given its consistency to the reference pattern.),

the set of parametric changes in the second mathematical relation being associated with a second diabetes defect having its own degree of severity **(col.: 4 lines: 33-41, col.: 5 lines: 59-61).**

The Examiner asserts that, according to column 5 lines 59-61, a mathematical equation is used it is inherent that variables within the formula contain magnitudes. Thus, it is inherent that the magnitudes are actually severity. Hereinafter, the Examiner asserts that Application's "severity" is in fact measurable within the mathematical formula. Therefor, it is inherently included in all math-based simulators wherein the inputs have variable magnitudes.

As per claim 6, Tresp discloses a method of claim 3, further comprising

converting at least one biological variable from the group of the first mathematical relation or second mathematical relation into a biological variable that evolves over time **(col.: 1 lines: 51-61 with emphasis on 55-57 "modeled in the form of a time series");** and

producing a series of simulated biological attributes based on the converted biological variable the series of simulated biological attributes being substantially consistent with a corresponding biological attribute associated with a reference pattern of diabetes, the series of simulated biological attributes representing the disease progression in the reference pattern of diabetes **(col.: 6 lines: 49-52, col.: 1 lines: 45-50 The computer model would inherently be substantially consistent when using a neural network and sufficient training data. As such it would be a valid model given its consistency to the reference pattern.).**

As per claim 7-9, the claims differ only in statutory basis to claims 1-3 (7-9 are the product for the method of claims 1-3).

As per claim 20, Tresp discloses a computer-readable medium having comparer-readable

instructions stored thereon that, upon execution by a processor, cause the processor to model a

disease state of diabetes, and further wherein the instructions comprise":

> defining a plurality of biological processes related to a disease state of diabetes including
>
> **(col.: 2 lines: 38-41 because the neural network is computerized it is inherent**
>
> **that code is used in order to define the formulas associated with the biological**
>
> **processes)**:
>
> defining a set of mathematical relations associated with a first biological process from the
>
> plurality of biological processes and associated with interactions among biological
>
> variables associated with the first biological process **(col.: 3 equation 1)**, and
>
> defining a set of mathematical relations associated with a second biological process from
>
> the plurality of biological processes and associated with interactions among biological
>
> variables associated with the second biological process **(col.: 3 equation 2)**,
>
> a first biological process from the plurality of biological processes being associated with
>
> metabolism of at least two from the group of carbohydrates, fats and proteins, a second
>
> biological process from the plurality of biological processes being associated with
>
> metabolism of glucose **(col.: 2 lines: 10-23, col.: 4 lines: 33-41)**.

As per claim 25, Tresp discloses a method for creating a computer model of diabetes,

comprising:

> identifying data relating to diabetes, the data relating changes in biological states to
>
> biological attributes of diabetes **(col.: 1 lines: 48-50 since the influencing variables**
>
> **are measured they are also inherently identified)**;
>
> identifying a plurality of biological processes related to the data, the plurality of biological
>
> processes defining at least one portion of the disease state of diabetes **(col.: 2 lines:**
>
> **24-26, col.: 4 lines: 33-41 "quantity of food" in the reference is directly related**
>
> **to the quantity of protein, referring to disease state, col. 4 lines 24-26: to**

warn a person a portion of the, or the whole, simulation result is used in

conjunction with reference material to identify whether the said result is

"showing" the disease state); and

combining the plurality of biological processes to form a simulation of at least one

biological attribute of diabetes in the context of fat metabolism **(col. 3 equation 3,**

col.: 2 lines: 10-23, col.: 4 lines: 33-41 Tresp's disclosure is broader than the

limitations set forth by this claim. Hence, it covers biological attributes of

diabetes in the context of fat metabolism.).

As per claim 26, Tresp discloses a method for creating a computer model of diabetes,

comprising:

identifying data relating to diabetes, the data relating changes in biological states to

biological attributes of diabetes **(col.: 1 lines: 48-50 since the influencing variables**

are measured they are also inherently identified);

identifying a plurality of biological processes related to the data, the plurality of biological

processes defining at least one portion of the disease state of diabetes **(col.: 2 lines:**

24-26, col.: 4 lines: 33-41 "quantity of food" in the reference is directly related

to the quantity of protein, referring to disease state, col. 4 lines 24-26: to

warn a person a portion of the, or the whole, simulation result is used in

conjunction with reference material to identify whether the said result is

"showing" the disease state); and

combining the plurality of biological processes to form a simulation of at least one

biological attribute of diabetes in the context of protein metabolism **(col. 3 equation 3,**

col.: 2 lines: 10-23, col.: 4 lines: 33-41 Tresp's disclosure is broader than the

limitations set forth by this claim. Hence, it covers biological attributes of

diabetes in the context of protein metabolism.).

As per claim 27, Tresp discloses a computer model of a disease state of diabetes, comprising:

a computer-readable memory storing **(col.: 2 lines: 38-41 See Examiner assertion below):**

instructions defining a set of biological processes related to the disease state of diabetes **(col.: 2 lines: 38-41 See Examiner assertion below),**

at least two biological processes from the set of biological processes being associated with a set of mathematical relationships related to interactions among biological variables associated with the biological processes **(col. 3, equations 1-3, col.: 4 lines: 33-41 it is inherent that the biological processes described by equations 1-3 are associated the said equations. As such, the reverse, in this case, also holds true. Since equation 3 is the combination of equation 1 and 2, there is an interaction and a relationship formed between the said two equations.),**

the instructions defining a simulation of at least one biological attribute of diabetes in the context of fat metabolism **(col. 3 equation 3, col.: 2 lines: 10-23, col.: 4 lines: 33-41 Tresp's disclosure is broader than the limitations set forth by this claim. Hence, it covers biological attributes of diabetes in the context of fat metabolism.);** and

a processor coupled to the computer-readable memory, the processor configured to execute the instructions **(col.: 2 lines: 38-41 See Examiner assertion below). Examiner assertion: Tresp is describing a neural network operating on a computer ("computerized neural network"). A computer inherently has a *processor* to *execute instructions* and for instructions to be executed. It is inherent that the instructions are first stored in *memory* in order to be executed.**

As per claim 28, Tresp discloses a computer model of a disease state of diabetes, comprising:

a computer-readable memory storing **(col.: 2 lines: 38-41 See Examiner assertion above):**

instructions defining a set of biological processes related to the disease state of diabetes

(col.: 2 lines: 38-41 See Examiner assertion above),

at least two biological processes from the set of biological processes being associated

with a set of mathematical relationships related to interactions among biological variables

associated with the biological processes **(col. 3, equations 1-3, col.: 4 lines: 33-41 it**

is inherent that the biological processes described by equations 1-3 are

associated the said equations. As such, the reverse, in this case, also holds

true. Since equation 3 is the combination of equation 1 and 2, there is an

interaction and a relationship formed between the said two equations.),

the instructions defining a simulation of at least one biological attribute of diabetes in the

context of protein metabolism **(col. 3 equation 3, col.: 2 lines: 10-23, col.: 4 lines:**

33-41 Tresp's disclosure is broader than the limitations set forth by this claim.

Hence, it covers biological attributes of diabetes in the context of protein

metabolism.).; and

a processor coupled to the computer-readable memory, the processor configured to

execute the instructions **(col.: 2 lines: 38-41 See Examiner assertion below).**

Examiner assertion: Tresp is describing a neural network operating on a

computer ("computerized neural network"). A computer inherently has a

***processor* to *execute instructions* and for instructions to be executed. It is**

inherent that the instructions are first stored in *memory* in order to be

executed.

Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Stephen Brown

("Brown" hereinafter) (US Patent 5,956,501).

As per claim 10, Brown discloses a computer-readable medium having computer-readable

instructions stored thereon that, upon execution by a processor, cause the processor to model a

disease state of diabetes, and further wherein the instructions comprise":

> defining a normal biological state through a set of biological processes, each biological
>
> process from the set of biological processes having its own associated parameter set, the
>
> set of biological processes being related to glucose metabolism in the context of multiple
>
> macronutrient metabolism **(col.: 6 line: 5 X(t_j) refers to biological state at time t_j;**
>
> **wherein, R(t_j) and R(t_i) is the set of biological processes and each process has**
>
> **its own associated parameter 't', col. 1 lines 15-20 with emphasis on line 16);**
>
> defining to provide a plurality of predefined defect indicators, each predefined defect
>
> indicator from the plurality of predefined defect indicators being uniquely associated with
>
> a defect from a plurality of defects associated with a disease state of diabetes, each
>
> defect from the plurality of defects being associated with at least one biological process
>
> from the set of biological processes **(col.: 4 top table.   Predefined defect indicators**
>
> **are shown in column 2 of the table);** and
>
> defining to receive a user-specified identification of a first defect indicator from the
>
> plurality of predefined defect indicators, a first defect from the plurality of defects being
>
> associated with the first defect indicator, the parameter set associated with each
>
> biological processes that is associated with the first defect being changed based on the
>
> user-specified identification **(col. 2 lines 57-59, col. 4 lines 58-61 input device for**
>
> **entering data, col.: 4 lines: 17-19 the self-care parameters would be entered**
>
> **by the user. Each defect ("self-care parameter") is associated with an input**
>
> **value, "parameter set" with each biological process (column 7, lines 60-62**
>
> **"metabolism rate")).**

As per claim 11, Brown discloses a computer-readable medium of claim 10, wherein the

instructions further comprise:

determining at least one simulated biological attribute based on the modified biological

process associated with the first defect, the simulated biological attribute being

substantially consistent with at least one corresponding biological attribute associated

with diabetes in a reference pattern of diabetes **(col.: 8 line: 38)**.

Examiner asserts that it is inherent that Brown's disclosed computer system

performing the simulation has code to do the above reference limitations, as

mentioned by Brown in abstract 4th line from the bottom.

As per claim 12, Brown discloses a computer-readable medium of claim 10, wherein the

instructions further comprise:

receiving a user-specified identification of a second defect indicator from the plurality of

predefined defect indicators, a second defect from the plurality of defects being

associated with the second defect indicator, the parameter set associated with each

biological processes that is associated with the second defect being changed based on

the user-specified identification **(col. 2 lines 57-59, col. 2 lines 57-59, col.: 4 lines:**

17-19 the self-care parameters would be entered by the user. Each defect

("self-care parameter") is associated with an input value, "parameter set"

with each biological process (column 7, lines 60-62 "hepatic and peripheral

insulin sensitivities")).

Examiner asserts that it is inherent that Brown's disclosed computer system

performing the simulation has code to do the above reference limitations, as

mentioned by Brown in abstract 4th line from the bottom.

As per claim 13, Brown discloses a computer-readable medium of claim 12, wherein:

the first defect has an associated severity based on the change to the at least one

associated parameter set **(col.: 7 line 66 to col.8 line 1 K_m refers to the associated**

severity); and

the second defect has an associated severity based on the change to the at least one

associated parameter set, the severity associated with the first defect being different

from the severity associated with the second defect **(col.: 8 lines: 1-6 "K₁" and "K₃").**

As per claim 14, Brown discloses a computer-readable medium of claim 12, wherein:

the first defect has an associated severity based on the change to the at least one

associated parameter set **(col.: 7 line 66 to col.8 line 1);** and

the second defect has an associated severity based on the change to the at least one

associated parameter set, the severity associated with the first defect being substantially

similar to the severity associated with the second defect **(col.: 8 lines: 1-6 "K₁" and**

"K₃").

As per claim 15, Brown discloses a computer-readable medium of claim 10, wherein the

instructions further comprise:

producing a simulated biological attribute based on the parameter set associated with

each biological processes that is associated with the first defect **(col.: 2 lines: 32-34),**

the simulated biological attribute being substantially consistent with biological attributes

of a reference pattern of diabetes **(col.: 2 lines: 10-13, col.: 7 lines: 22-30 The**

simulation would inherently be substantially consistent when using Brown's

disclosed method and apparatus with sufficient input data. As such it would be

a valid model given its consistency to the reference pattern.).

Claims 16-19, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by David Rivonelli,

"Rivonelli" hereinafter, (U.S. Patent 6,246,975).

As per claim 16, Rivonelli discloses a computer executable software code, comprising:

code to provide a plurality of predefined defect indicators, each predefined defect

indicator from the plurality of predefined defect indicators being uniquely associated with

a defect from a plurality of defects associated with a disease state, each defect from the

plurality of defects being associated with at least one biological process from a set of

biological processes **(col.: 16 lines: 17-18, col.: 23 lines: 30-36 When the**

generation method is performed, it provides a description of all of the findings

(defects)),

the set of biological processes being related to glucose metabolism in the context of

multiple macronutrient metabolism **(col.: 12 lines: 63-67)**

code to receive a user-specified identification of a first defect indicator from the plurality

of predefined defect indicators, a first defect from the plurality of defects being

associated with the first defect indicator, the first defect being associated with at least

one biological process and its associated parameter set, the at least one parameter set

associated with the first defect being changed based on the user-specified identification;

(col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified" because the

information is collected then transferred into computer readable format, col.:

16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the

second defect may be "cardiovascular disease"), and code

to receive a user-specified identification of a second defect indicator from the plurality of

predefined defect indicators, a second defect from the plurality of defects being

associated with the second defect indicator, the second defect being associated with at

least one biological process and its associated parameter set, the at least one parameter

set associated with the second defect being changed based on the user-specified

identification **(col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified" because**

the information is collected then transferred into computer readable format,

col.: 16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein

the second defect may be "disease of glucose intolerance").

The Examiner asserts that a change in one biological processes of an individual will very

least be associated with another biological process for the fact that it is in the same

individual. As such their associatively will be generated by being "part" of one entity.

As per claim 17, Rivonelli discloses a computer executable software code of claim 16, wherein:

the first defect having an associated severity based on the change to the at least one

associated parameter set **(col.: 12 lines: 12-21),**

the second defect having an associated severity based on the change to the at least one

associated parameter set, the severity associated with the first defect being different

from the severity associated with the second defect **(col.: 12 lines: 12-21, col.: 13**

lines: 51-53).

As per claim 18, Rivonelli discloses a computer executable software code of claim 16, further

comprising:

code to define a normal biological state through the set of biological processes, each

biological process from the set of biological processes being associated with its own

parameter set **(col.: 22 lines: 60-65).**

As per claim 19, Rivonelli discloses a computer executable software code of claim 16, wherein

the plurality of defects are associated with type 2 diabetes **(col.: 6 lines: 58-62).**

As per claim 24, Rivonelli discloses a method for creating a computer model of diabetes,

comprising:

receiving a plurality of user-selected indications to define a plurality of biological

processes, each biological process from the plurality of biological processes being based

on data that relates to changes in biological states to biological attributes of diabetes

(col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified" because the

information is collected then transferred into computer readable format, col.:

16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the

second defect may be "cardiovascular disease");

producing a representation of the plurality of biological processes based on the user-

selected indications, the plurality of biological processes defining at least one portion of

the disease state of diabetes **(Abstract lines 1-4, The Examiner asserts that**

"reproducing a representation ... based on the user-selected indications"

means simulating the system based on user inputs;

producing a simulated biological attribute associated with at least one biological attribute

of diabetes based on the combined plurality of biology processes **(col.: 13 lines: 51-**

53, Abstract lines 1-4); and

assessing a validity of the computer model based on a comparison between the

simulated biological attribute and a corresponding biological attribute associated with a

reference pattern of diabetes **(Abstract 1-4 "simulating" The computer model**

would inherently be substantially consistent because it uses predetermined

criteria as well as user-input as input into the simulation program.

Additionally, the Examiner asserts that the assessment can be performed by

the examinee and as such references column 12, lines 50-52 with emphasis on

the examinee's conclusion about the simulation.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or
> described as set forth in section 102 of this title, if the differences between the subject matter
> sought to be patented and the prior art are such that the subject matter as a whole would
> have been obvious at the time the invention was made to a person having ordinary skill in the
> art to which said subject matter pertains. Patentability shall not be negatived by the manner
> in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under

35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention

was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential

35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volker Tresp

("Tresp" hereinafter) (US Patent 6,272,480) as applied to claim 20 above, and further in view of

David Rivonelli, Rivonelli hereinafter, (U.S. Patent 6,246,975).

As per claim 21, Tresp substantially discloses the computer-readable medium of claim 20,

defining a set of parametric changes for a biological process **(Tresp, col.: 5 lines: 44-49**

training data, when introduced into the neural network will serve as a parametric

change in the mathematical relations). Tresp does not specifically disclose the receiving

user-specified identification of a first defect indicator.

However, Rivonelli discloses an analogous system that includes steps to receive a user-specified

input of a defect indicator **(Rivonelli, col.: 8 lines: 22-26 "user-specified" because the**

information is collected then transferred into computer readable format, col.: 16

lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the a defect

may be "cardiovascular disease"). It would have been obvious to one of ordinary skill in the

art, at the time of Applicants' invention, to combine the teachings of the cited references. In

fact, motivation combine would have been to allow the examinee to have a much simpler

interface through the set of predefined findings (defect indicators) in order to lessen the amount

of work needed to be performed by the examinee or physician.

As per claim 22, Tresp discloses all limitations to claim 21. Tresp however does not specifically

disclose receiving a user-specified identification of a second defect indicator from the plurality of

predefined defect indicators, the second defect indicator from the plurality of defect indicators

being uniquely associated with a second defect from the plurality of defects that is associated

with the disease state of diabetes, the second defect being associated with at least one biological

process and its associated parameter set, the at least one parameter set associated with the

second defect being changed based on the user-specified identification; and the first defect

having an associated severity based on the change to the at least one associated parameter set,

the second defect having an associated severity based on the change to the at least one

associated parameter set, the severity associated with the first defect being different from the

severity associated with the second defect (col.: 12 lines: 12-21, col.: 13 lines: 51-53). Rivonelli

however discloses an analogous diabetes simulation system having the said features **(col.: 12

lines: 50-52, col.: 8 lines: 22-26 "user-specified" because the information is collected

then transferred into computer readable format, col.: 16 lines: 17-18 findings

correlate to defects, col. 15 lines 64-67 wherein the second defect may be "disease of

glucose intolerance")**. It would have been obvious to one of ordinary skill in the art, at the

time of Applicants' invention, to combine the teachings of the cited references. In fact,

motivation combine would have been to allow the examinee to have a much simpler interface

through the set of predefined findings (defect indicators) in order to lessen the amount of work

needed to be performed by the examinee or physician.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Volker Tresp ("Tresp"

hereinafter) (US Patent 6,272,480) as applied to claim 20 above, and further in view of AIDA

Case Selector and AIDA Explanations (See IDS for reference information).

As per claim 23, Tresp does not specifically discuss the limitations of the claim. However, AIDA

implemented an analogous system having

> receiving a user selection of a link representation from a set of predefined link
>
> representations, each predefined link representation in the set of predefined link
>
> representations being associated with a different mathematical relationship, the user-
>
> selected link representation being associated with the interrelationship between a first

biological variable and a second biological variable **(AIDA Case Selector, page: 3 reference 1, page 4 reference 2),** a first link representation from the set of predefined link representations being a representation of the first biological variable having an effect on the second biological variable **(AIDA Explanations, page 3, Section "Blood glucose level (BGL)"),** a second link representation from the set of predefined link representations being a representation of instances of the first biological variable being converted to instances of the second biological variable **(AIDA Explanations, page 1, Section "Blood glucose units").** It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to combine the references in order to allow for remote diabetes diagnosis and simulation, as is performed and suggested by AIDA. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the references in order to allow for research of information related to the particulars of diabetes through a simple interface, as is also performed and suggested by AIDA.

Conclusion

Claims 1-28 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Silver whose telephone number is (571) 272-8634. The examiner can normally be reached on Monday thru Friday, 10am to 6:30pm.
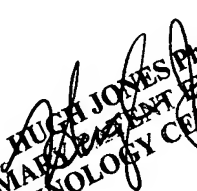
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kamini Shah can be reached on 571-272-2279. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

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applications is available through Private PAIR only. For more information about the PAIR system,

see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Silver
Patent Examiner
Art Unit 2128

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